

REMARKS

The Claims in the application are 21-27, 29-30, 35-36,38, 39, 49,51, 54-56 and 60-62. Claims 61-62 have been amended to depend from Claim 21. No new matter has been added.

In the Office Action the Examiner has requested restriction between product and process claims. In particular, the Examiner stated that new claims 61-62 are directed to a different invention, namely the examined invention is directed to a composition and new claims 61-62 are directed to a method of using the examined composition. Although the language tracks Claim 21 almost identically, in order to advance prosecution of the present application the Applicants have amended Claims 61-62 to depend from Claim 21 and therefore Claims 61-62 clearly contain all of the limitations and attributes of Claim 21. Accordingly, the Applicants respectfully contend that since the process claims include all of the limitations of product claim 21, claims 61-62 should also be found to be allowable upon allowance of the product claims.

In the Office Action, the Examiner maintained the objection to the specification. Although the specification was amended to include a Brief Description of the Invention section, the Examiner contends that it was inserted in the application at an inappropriate spot. In making this objection, the Examiner refers to 37 C.F.R. §1.77(b) as support for the objection. The Applicants respectfully point out to the Examiner that 37 C.F.R. §1.77(b) provides a suggested arrangement of the specification, not a mandatory arrangement. However, in an effort to advance prosecution of the application, the specification has been amended so as to insert the "*Brief Description of the Invention*" section

prior to the "*Detailed Description of the Invention*" section of the current application. In view of the foregoing, the Applicants respectfully request that the objection be reconsidered and withdrawn.

In the Office Action, the Examiner has maintained the rejection of Claims 49 under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement. In particular, the Examiner contends that the limitation "of less than or equal to 1000,000 daltons" is new matter. For reasons presented below, the Applicants respectfully disagree.

The limitation "of less than or equal to 100,000 daltons" refers to hydrolyzed fragments of sericin used in the present invention. The Examiner acknowledges that the specification fully supports an unhydrolyzed sericin protein having a molecular weight of 100,000 daltons but contends that hydrolyzed fragments of the sericin protein having an average molecular weight of less than 100,000 daltons is not supported by the specification.

As stated in the previous response and reiterated again, the specification clearly states that the claimed compositions can contain unhydrolyzed sericin as well as hydrolyzed sericin, (referred to as "sericin L") and since the molecular weight of unhydrolyzed sericin is 100,000 daltons, the specification therefore teaches compositions comprising unhydrolyzed 100,000 daltons sericin protein and hydrolyzed fragments of the sericin protein that by definition must be less than less than 100,000 daltons. Since the fragments are part of the whole.

In addition, Preparation Example 2 teaches the production of sericin L (hydrolyzed) having an average molecular weight of 20,000 daltons and Example 7 teaches the effectiveness of sericin L on controlling colon cancer.

The fact that sericin L has an average molecular weight of 20,000 daltons and a purity of 90% or higher indicates that both larger and smaller hydrolyzed fragments of the 20,000 daltons sericin fragment are present in the hydrolyzed portion of the preparation of the present invention. In addition, since the technique used to obtain the hydrolyzed fragments of the sericin molecule is non-specific, namely sodium carbonate in water (pH 11), the procedure allows for fragments of many different sizes to be formed. For all of the foregoing reasons, Applicants respectfully contend that the phrase "of less than or equal to 1000,000 daltons" as appears in the claims is fully supported by the specification and the rejection of Claim 49 as new matter must be reconsidered and withdrawn.

In the Office Action, Claims 21-27, 29-30, 35-36, 49,51 and 54-56 remain rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for making powder sericin with the molecular weight greater than 100 kDa with 90% purity or higher, the Examiner alleges that the specification does not reasonably provide enablement for making sericin powder with any other weight of less than 100kDa. (See Office Action, page 6- page 7).

As stated in the previous response, since the specification teaches that oral preparations of the present invention can contain unhydrolyzed sericin as well as hydrolyzed sericin, and since the Examiner has acknowledged that sericin having a molecular weight of 100,000 daltons is enabled, and the specification teaches a method of hydrolyzing the 100kDa sericin protein into smaller fragments, the specification therefore teaches oral composition comprising hydrolyzed fragments of the sericin protein that by definition must be less than less than

100,000 daltons. The process for obtaining these fragments is described in the preparation Example 2 of the present invention. In Example 2 the unhydrolyzed sericin powder of Example 1 is subjected to treatment in a 0.2% solution of sodium bicarbonate at a pH of 11-12 at 95 degrees Celsius for two hours. The resultant extract was filtered and the hydrolyzed sericin product was obtained. Since this procedure does not utilize enzyme degradation, but utilization chemical (basic ~pH 11) and heat catalysis of the sericin protein, the sizes of the fragments produced would not be expected to be of a specific size and weight but rather would be expected to be of various sizes. Therefore, the full range of fragments can be obtained, each weighing less than the full sericin protein (100kDa).

This is further supported in the preparation described in Example 2 that teaches the production of sericin L (hydrolyzed) having an average molecular weight of 20,000 daltons and Example 7 that teaches the effectiveness of sericin L on controlling colon cancer. The fact that sericin L has an average molecular weight of 20,000 daltons and a purity of 90% or higher indicates that both larger and smaller hydrolyzed fragments of the 20,000 daltons sericin fragment are present in the hydrolyzed portion of the preparation of the present invention.

In maintaining the rejection, the Examiner again stated that Teramoto et al. recites "that three kinds of sericins exist: one greater than 250 kDa, about 180 kDa, and about 100 kDa." (See Office Action pages 6-7). Applicants respectfully point out that when citing to a portion of a reference the complete reference must be considered for all that it teaches. For example, although Teramoto states "that three kinds of sericins exist : one greater than 250kDa,

about 180 kDa, and about 100 kDa," how these three different "kinds of sericin" were obtained must be considered. A review of this document indicates that the procedure used to obtain the recited sericin molecules in Teramoto is significantly different than the procedure used in the present invention and therefore it would be expected that different sericin molecules and/or fragments of sericin would be obtained. In addition, in considering the reference for all that it teaches, the Applicants would like to direct the Examiner's attention to Fig. 1 of Teramoto as well as the rest of the sentence reciting the "three kinds of sericins" referenced above and shown in the SDS PAGE of Fig. 1 of Teramoto.

In particular, the end of the sentence reciting the three kinds of sericins relied on by the Examiner to show that a 20,000 Da sized sericin is not described in Teramoto, actually refers to "intact sericin," and not hydrolyzed fragments. (See Teramoto at page 845, left column). Therefore this does not show that fragments of sericin do not exist. Moreover a close observation of the SDS PAGE of Fig. 1 in Teramoto clearly shows additional separation bands other than the three molecular weights referred to above. This clearly indicates that fragments of the three prominent bands, i.e. with average molecular weights less than 100 kDa, do exist. In fact, lanes 1 and 2 of Fig. 1 clearly show the presence of a band below the 50Kda control marker, possibly at 20 kDa -30kDa or less, however, this portion of the SDS PAGE is cut off in the photograph of the SDS PAGE and full identification can not be confirmed. Therefore, Teramoto, when reviewed in total, does not indicate that fragments having an average molecular weight of less than 100 kDa, i.e. 20 kDa, do not exist but instead supports the claimed invention that fragments of various sizes can be produced and isolated

(see lanes 1 and 2 of the SDS PAGE). Teramoto also confirms that the 100 kDa protein of sericin does exist and can be isolated.

In maintaining this rejection, the Examiner again refers to Takasu. In particular, the Examiner quotes a section of the first paragraph of page 2715, right column, which states “no effective separation of sericins was established” and uses this to support a conclusion that even two years after the filing of the instant application, sericin was not effectively separated. However, as with Teramoto discussed above, when relying on a reference the complete reference must be reviewed. A review of this reference reveals that at the end of column 1 of page 2715 it states that “at least 15 different sericins ranging from about 20 to 220 kDa in the anterior portion of the middle silk gland” was reported. Therefore, the Examiner’s reliance on Takasu to show that there was no effective separation of sericin achieved even two years after the filing date of the instant invention, is incorrect. In fact, Takasu actually supports the Applicants finding that many different fragments of sericin can be isolated.

In view of the foregoing, Applicants respectfully assert that the claims are fully enabled by the specification and respectfully request that the rejection of Claims 21-27, 29-30, 35-36, 49,51 and 54-56 under 35 U.S.C. §112, first paragraph, be reconsidered and withdrawn.

In the Office Action, Claims 21-27, 29-31, 34, 36-39, 49-59 remain rejected under 35 U.S.C. § 102(e) as being anticipated by US Patent No. 6,165, 982 (Yamada et al.).

Prior to addressing the prior art rejection, Applicants respectfully note that no art has been cited against Claim 60 and therefore, should the formal rejection

of Claim 60 be overcome, and Claim 60 re-written into independent form, Claim 60 would be in condition for allowance.

As stated above claim 21 has been amended to require a **mineral mix** contain minerals that assist in the absorption of minerals during digestion. In maintaining the rejection the Examiner states that Yamada et al. teaches all of the limitations of the Claims including *aluminum sulfate*, which the Examiner states is an important mineral and sites to "The Sulfates Class" to support this assertion. A printout of "The Sulfates Class" was not provided and the Applicants tried to find a listing of "aluminum sulfate" on this site but was unsuccessful. Therefore a copy of this reference is requested.

Instead, the Applicants provide a Material Safety Data Sheet (MSDS) for Aluminum sulfate that indicates that any ingestion of this material would "*causes irritation to the gastrointestinal tract. Symptoms may include nausea, vomiting and diarrhea. There have been two cases of fatal human poisoning from ingestion of 30 grams of alum.*" (See highlighted section of MSDS for aluminum sulfate attached herewith). Since aluminum sulfate may cause death if ingested and the claims are directed to an **oral** composition for treating colon cancer, it would be hard to believe that aluminum sulfate falls within the meaning of the phrase "mineral mix."

In addition, a review the section in Yamada cited by the Examiner (of col. 4, ln. 66), reveals that "aluminum sulfate" is not disclosed as recited in the rejection, but instead recites "potassium aluminum sulfate." However, the MSDS for this chemical also teaches away from ingestion of this chemical. (See highlighted section of MSDS) Therefore, even if the mineral being referred to by

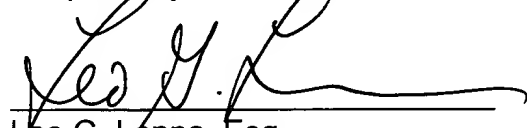
the Examiner in the rejection was actually potassium aluminum sulfate, for the same reasons discussed above for aluminum sulfate, potassium aluminum sulfate can not be considered to teach a mineral mix as recited in the oral preparation as claimed. Moreover, inclusion of such chemicals actually teach away from an oral preparation of any type.

In addition, the Claims require a mineral "mix" which means more than one mineral. The Examiner has only referred to one mineral. The Applicants respectfully assert that one mineral does not make a mineral mix. For this additional reason, the rejection of Claims 21-27, 29-31, 34, 36-39, 49-59 under 35 U.S.C. § 102(e) be reconsidered and withdrawn.

Therefore, in view of the forgoing amendment, and accompanying remarks, it is respectfully submitted all claims pending herein are in condition for allowance. Please contact the undersigned attorney should there be any questions.

Early favorable action is earnestly solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Leo G. Lenna', written over a horizontal line.

Leo G. Lenna, Esq.

Reg. No. 42,796

Attorney for Applicants

DILWORTH & BARRESE, LLP

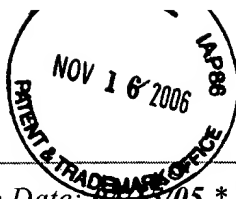
333 Earle Ovington Blvd.

Uniondale, New York 11553

Phone: 516-228-8484

Facsimile: 516-228-8516

LGL/vjs

MSDS Number: **A2856** * * * * * Effective Date: 07/13/05 * * * * * Supersedes: 07/07/04**MSDS****Material Safety Data Sheet**

From: Mallinckrodt Baker, Inc.
222 Red School Lane
Phillipsburg, NJ 08865

**Mallinckrodt
CHEMICALS**

24 Hour Emergency Telephone: 800-859-2151
CHEMTREC: 1-800-424-9300

National Response in Canada
CANUTEC: 613-996-6666

Outside U.S. and Canada
Chemtrec: 703-527-3887

NOTE: CHEMTREC, CANUTEC and National Response Center emergency numbers to be used only in the event of chemical emergencies involving a spill, leak, fire, exposure or accident involving chemicals.

All non-emergency questions should be directed to Customer Service (1-800-552-2537) for assistance.

ALUMINUM POTASSIUM SULFATE

1. Product Identification

Synonyms: Sulfuric acid, aluminum potassium salt (2:1:1), dodecahydrate; potassium alum dodecahydrate; Alum Potassium USP Powder TAC; Potassium alum; Potash alum; Alum; Kalinite

CAS No.: 10043-67-1 (Anhydrous) 7784-24-9 (Dodecahydrate)

Molecular Weight: 474.38

Chemical Formula: $\text{AlK}(\text{SO}_4)_2 \cdot 12\text{H}_2\text{O}$

Product Codes:

J.T. Baker: 0546, 0547

Mallinckrodt: 3216

2. Composition/Information on Ingredients

Ingredient	CAS No	Percent	Hazardous
Sulfuric Acid, Aluminum Potassium Salt (2:1:1)	10043-67-1	98 - 100%	Yes

3. Hazards Identification

Emergency Overview

WARNING! HARMFUL IF SWALLOWED OR INHALED. CAUSES IRRITATION TO SKIN, EYES AND RESPIRATORY TRACT.

SAF-T-DATA^(tm) Ratings (Provided here for your convenience)

Health Rating: 2 - Moderate

Flammability Rating: 0 - None

Reactivity Rating: 1 - Slight

Contact Rating: 2 - Moderate

Lab Protective Equip: GOGGLES; LAB COAT; VENT HOOD; PROPER GLOVES

Storage Color Code: Green (General Storage)

Potential Health Effects

This material hydrolyzes in water to form sulfuric acid, which is responsible for the irritating effects given below.

Inhalation:

Causes irritation to the respiratory tract. Symptoms may include coughing, shortness of breath.

Ingestion:

Causes irritation to the gastrointestinal tract. Symptoms may include nausea, vomiting and diarrhea. There have been two cases of fatal human poisonings from ingestion of 30 grams of alum.

Skin Contact:

Causes irritation to skin. Symptoms include redness, itching, and pain.

Eye Contact:

Causes irritation, redness, and pain.

Chronic Exposure:

No information found.

Aggravation of Pre-existing Conditions:

No information found.

4. First Aid Measures

Inhalation:

Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

Ingestion:

If swallowed, DO NOT INDUCE VOMITING. Give large quantities of water. Never give anything by mouth to an unconscious person. Get medical attention immediately.

Skin Contact:

Wipe off excess material from skin then immediately flush skin with plenty of water for at least 15 minutes. Remove contaminated clothing and shoes. Get medical attention. Wash

clothing before reuse. Thoroughly clean shoes before reuse.

Eye Contact:

Immediately flush eyes with plenty of water for at least 15 minutes, lifting upper and lower eyelids occasionally. Get medical attention.

5. Fire Fighting Measures

Fire:

Not considered to be a fire hazard.

Explosion:

Not considered to be an explosion hazard.

Fire Extinguishing Media:

Use any means suitable for extinguishing surrounding fire. Keep in mind that addition of water can cause the formation of sulfuric acid.

Special Information:

In the event of a fire, wear full protective clothing and NIOSH-approved self-contained breathing apparatus with full facepiece operated in the pressure demand or other positive pressure mode.

6. Accidental Release Measures

Cover spill with sodium bicarbonate or soda ash and mix. Ventilate area of leak or spill. Keep unnecessary and unprotected people away from area of spill. Wear appropriate personal protective equipment as specified in Section 8. Spills: Pick up and place in a suitable container for reclamation or disposal, using a method that does not generate dust.

7. Handling and Storage

Keep in a tightly closed container, stored in a cool, dry, ventilated area. Protect against physical damage. Isolate from incompatible substances. Containers of this material may be hazardous when empty since they retain product residues (dust, solids); observe all warnings and precautions listed for the product.

8. Exposure Controls/Personal Protection

Airborne Exposure Limits:

-OSHA Permissible Exposure Limit (PEL):

2 mg/m³ (TWA) soluble salts as Al

-ACGIH Threshold Limit Value (TLV):

2 mg/m³ (TWA) soluble salts as Al

Ventilation System:

A system of local and/or general exhaust is recommended to keep employee exposures below the Airborne Exposure Limits. Local exhaust ventilation is generally preferred because it can control the emissions of the contaminant at its source, preventing dispersion of it into the general work area. Please refer to the ACGIH document, *Industrial Ventilation, A Manual of Recommended Practices*, most recent edition, for details.

Personal Respirators (NIOSH Approved):

If the exposure limit is exceeded and engineering controls are not feasible, a half facepiece particulate respirator (NIOSH type N95 or better filters) may be worn for up to ten times the exposure limit or the maximum use concentration specified by the appropriate regulatory agency or respirator supplier, whichever is lowest. A full-face piece particulate respirator (NIOSH type N100 filters) may be worn up to 50 times the exposure limit, or the maximum use concentration specified by the appropriate regulatory agency, or respirator supplier, whichever is lowest. If oil particles (e.g. lubricants, cutting fluids, glycerine, etc.) are present, use a NIOSH type R or P filter. For emergencies or instances where the exposure levels are not known, use a full-facepiece positive-pressure, air-supplied respirator.

WARNING: Air-purifying respirators do not protect workers in oxygen-deficient atmospheres.

Skin Protection:

Wear impervious protective clothing, including boots, gloves, lab coat, apron or coveralls, as appropriate, to prevent skin contact.

Eye Protection:

Use chemical safety goggles and/or full face shield where dusting or splashing of solutions is possible. Maintain eye wash fountain and quick-drench facilities in work area.

9. Physical and Chemical Properties

Appearance:

Colorless crystals.

Odor:

Odorless.

Solubility:

14% in water, 333% in boiling water

Density:

1.73

pH:

3.3 (0.2 M solution)

% Volatiles by volume @ 21C (70F):

0

Boiling Point:

ca. 200C (ca. 392F) Loses water

Melting Point:

92.5C (198F)

Vapor Density (Air=1):

No information found.

Vapor Pressure (mm Hg):

No information found.

Evaporation Rate (BuAc=1):

No information found.

10. Stability and Reactivity

Stability:

Stable under ordinary conditions of use and storage.

Hazardous Decomposition Products:

Hydrolyzes to form dilute sulfuric acid. Toxic and corrosive oxides of sulfur may be formed when heated to decomposition.

Hazardous Polymerization:

Will not occur.

Incompatibilities:

Corrosive to metals in the presence of water.

Conditions to Avoid:

Moisture and incompatibles.

11. Toxicological Information

Investigated as a reproductive effector.

-----\Cancer Lists\-----			
Ingredient	---NTP Carcinogen---		IARC Category
	Known	Anticipated	
Sulfuric Acid, Aluminum Potassium Salt (2:1:1) (10043-67-1)	No	No	None

12. Ecological Information

Environmental Fate:

No information found.

Environmental Toxicity:

No information found.

13. Disposal Considerations

Whatever cannot be saved for recovery or recycling should be managed in an appropriate and approved waste disposal facility. Processing, use or contamination of this product may change the waste management options. State and local disposal regulations may differ from

federal disposal regulations. Dispose of container and unused contents in accordance with federal, state and local requirements.

14. Transport Information

Not regulated.

15. Regulatory Information

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-----\Chemical Inventory Status - Part 1\-----
Ingredient                                     TSCA  EC   Japan  Australia
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Sulfuric Acid, Aluminum Potassium Salt (2:1:1)  Yes  Yes   Yes    Yes
(10043-67-1)

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-----\Chemical Inventory Status - Part 2\-----
Ingredient                                     Korea  DSL   NDSL   Phil.
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Sulfuric Acid, Aluminum Potassium Salt (2:1:1)  Yes   Yes   No     Yes
(10043-67-1)

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-----\Federal, State & International Regulations - Part 1\-----
Ingredient                                     -SARA 302-  -SARA 313-----
RQ      TPQ      List  Chemical Catg.
-----
Sulfuric Acid, Aluminum Potassium Salt      No    No     No     No
(2:1:1) (10043-67-1)

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-----\Federal, State & International Regulations - Part 2\-----
Ingredient                                     CERCLA  -RCRA-  -TSCA-
261.33  8(d)
-----
Sulfuric Acid, Aluminum Potassium Salt      No      No      No
(2:1:1) (10043-67-1)

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Chemical Weapons Convention: No TSCA 12(b): No CDTA: No
 SARA 311/312: Acute: Yes Chronic: No Fire: No Pressure: No
 Reactivity: No (Pure / Solid)

Australian Hazchem Code: None allocated.

Poison Schedule: None allocated.

WHMIS:

This MSDS has been prepared according to the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all of the information required by the CPR.

16. Other Information

NFPA Ratings: Health: 1 Flammability: 0 Reactivity: 0

Label Hazard Warning:

WARNING! HARMFUL IF SWALLOWED OR INHALED. CAUSES IRRITATION TO SKIN, EYES AND RESPIRATORY TRACT.

Label Precautions:

Avoid breathing dust.

Keep container closed.

Use only with adequate ventilation.

Wash thoroughly after handling.

Avoid contact with eyes, skin and clothing.

Label First Aid:

If swallowed, DO NOT INDUCE VOMITING. Give large quantities of water. Never give anything by mouth to an unconscious person. If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. In case of contact, wipe off excess material from skin then immediately flush eyes or skin with plenty of water for at least 15 minutes. Remove contaminated clothing and shoes. Wash clothing before reuse. In all cases, get medical attention.

Product Use:

Laboratory Reagent.

Revision Information:

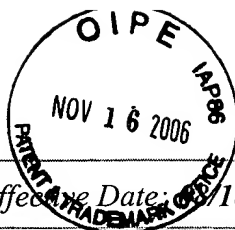
MSDS Section(s) changed since last revision of document include: 3.

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Prepared by: Environmental Health & Safety

Phone Number: (314) 654-1600 (U.S.A.)



MSDS Number: A2914 * * * * * Effective Date: 08/18/05 * * * * * Supersedes: 08/10/04

MSDS**Material Safety Data Sheet**

From: Mallinckrodt Baker, Inc.
222 Red School Lane
Phillipsburg, NJ 08865

M Mallinckrodt
CHEMICALS



24 Hour Emergency Telephone: 800-859-2151
CHEMTREC: 1-800-424-9300

National Response in Canada
CANUTEC: 613-996-6666

Outside U.S. and Canada
Chemtrec: 703-527-3887

NOTE: CHEMTREC, CANUTEC and National Response Center emergency numbers to be used only in the event of chemical emergencies involving a spill, leak, fire, exposure or accident involving chemicals.

All non-emergency questions should be directed to Customer Service (1-800-562-2537) for assistance.

ALUMINUM SULFATE

1. Product Identification

Synonyms: Sulfuric acid, aluminum salt (3:2), octadeca hydrate; Cake alum; Patent alum

CAS No.: 10043-01-3 (Anhydrous) 7784-31-8 (Octadecahydrate)

Molecular Weight: 666.44

Chemical Formula: $Al_2(SO_4)_3 \cdot 18H_2O$

Product Codes:

J.T. Baker: 0564

Mallinckrodt: 3208

2. Composition/Information on Ingredients

Ingredient	CAS No	Percent	Hazardous
Aluminum Sulfate	10043-01-3	98 - 100%	Yes

3. Hazards Identification

Emergency Overview

WARNING! HARMFUL IF SWALLOWED OR INHALED. CAUSES IRRITATION TO SKIN, EYES AND RESPIRATORY TRACT.

SAF-T-DATA^(tm) Ratings (Provided here for your convenience)

Health Rating: 2 - Moderate

Flammability Rating: 0 - None

Reactivity Rating: 1 - Slight

Contact Rating: 2 - Moderate

Lab Protective Equip: GOGGLES; LAB COAT; VENT HOOD; PROPER GLOVES

Storage Color Code: Green (General Storage)

Potential Health Effects

This material hydrolyzes in water to form sulfuric acid, which is responsible for the irritating effects given below.

Inhalation:

Causes irritation to the respiratory tract. Symptoms may include coughing, shortness of breath.

Ingestion:

Causes irritation to the gastrointestinal tract. Symptoms may include nausea, vomiting and diarrhea. There have been two cases of fatal human poisonings from ingestion of 30 grams of alum.

Skin Contact:

Causes irritation to skin. Symptoms include redness, itching, and pain.

Eye Contact:

Causes irritation, redness, and pain.

Chronic Exposure:

No information found.

Aggravation of Pre-existing Conditions:

No information found.

4. First Aid Measures

Inhalation:

Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

Ingestion:

If swallowed, DO NOT INDUCE VOMITING. Give large quantities of water. Never give anything by mouth to an unconscious person. Get medical attention immediately.

Skin Contact:

Wipe off excess material from skin then immediately flush skin with plenty of water for at least 15 minutes. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.

Eye Contact:

Immediately flush eyes with plenty of water for at least 15 minutes, lifting upper and lower eyelids occasionally. Get medical attention.

5. Fire Fighting Measures

Fire:

Not considered to be a fire hazard.

Explosion:

Not considered to be an explosion hazard.

Fire Extinguishing Media:

Keep in mind that addition of water can cause the formation of sulfuric acid.

Special Information:

In the event of a fire, wear full protective clothing and NIOSH-approved self-contained breathing apparatus with full facepiece operated in the pressure demand or other positive pressure mode.

6. Accidental Release Measures

Ventilate area of leak or spill. Keep unnecessary and unprotected people away from area of spill. Wear appropriate personal protective equipment as specified in Section 8. Spills: Pick up and place in a suitable container for reclamation or disposal, using a method that does not generate dust. Cover spill with sodium bicarbonate or soda ash and mix. US Regulations (CERCLA) require reporting spills and releases to soil, water and air in excess of reportable quantities. The toll free number for the US Coast Guard National Response Center is (800) 424-8802.

7. Handling and Storage

Keep in a tightly closed container, stored in a cool, dry, ventilated area. Protect against physical damage. Isolate from incompatible substances. Aluminum sulfate absorbs moisture and becomes a safety hazard when spilled because it absorbs moisture and becomes slippery. Containers of this material may be hazardous when empty since they retain product residues (dust, solids); observe all warnings and precautions listed for the product.

8. Exposure Controls/Personal Protection

Airborne Exposure Limits:

-OSHA Permissible Exposure Limit (PEL):
2 mg/m³ (TWA) soluble salts as Al

-ACGIH Threshold Limit Value (TLV):

2 mg/m³ (TWA) soluble salts as Al

Ventilation System:

A system of local and/or general exhaust is recommended to keep employee exposures below the Airborne Exposure Limits. Local exhaust ventilation is generally preferred because it can control the emissions of the contaminant at its source, preventing dispersion of it into the general work area. Please refer to the ACGIH document, *Industrial Ventilation, A Manual of Recommended Practices*, most recent edition, for details.

Personal Respirators (NIOSH Approved):

If the exposure limit is exceeded and engineering controls are not feasible, a half facepiece particulate respirator (NIOSH type N95 or better filters) may be worn for up to ten times the exposure limit or the maximum use concentration specified by the appropriate regulatory agency or respirator supplier, whichever is lowest. A full-face piece particulate respirator (NIOSH type N100 filters) may be worn up to 50 times the exposure limit, or the maximum use concentration specified by the appropriate regulatory agency, or respirator supplier, whichever is lowest. If oil particles (e.g. lubricants, cutting fluids, glycerine, etc.) are present, use a NIOSH type R or P filter. For emergencies or instances where the exposure levels are not known, use a full-facepiece positive-pressure, air-supplied respirator.

WARNING: Air-purifying respirators do not protect workers in oxygen-deficient atmospheres.

Skin Protection:

Wear impervious protective clothing, including boots, gloves, lab coat, apron or coveralls, as appropriate, to prevent skin contact.

Eye Protection:

Use chemical safety goggles and/or full face shield where dusting or splashing of solutions is possible. Maintain eye wash fountain and quick-drench facilities in work area.

9. Physical and Chemical Properties

Appearance:

Colorless crystals.

Odor:

Odorless.

Solubility:

87 g/100 cc water @ 0C (32F).

Specific Gravity:

1.69 @ 17C/4C

pH:

No information found.

% Volatiles by volume @ 21C (70F):

0

Boiling Point:

No information found.

Melting Point:

87C (189F) Decomposes.

Vapor Density (Air=1):

No information found.

Vapor Pressure (mm Hg):

No information found.

Evaporation Rate (BuAc=1):

No information found.

10. Stability and Reactivity

Stability:

Stable under ordinary conditions of use and storage.

Hazardous Decomposition Products:

Hydrolyzes to form dilute sulfuric acid. Toxic and corrosive oxides of sulfur may be formed when heated to decomposition.

Hazardous Polymerization:

Will not occur.

Incompatibilities:

Corrosive to metals in the presence of water.

Conditions to Avoid:

Moisture and incompatibles.

11. Toxicological Information

Anhydrous Material: Oral mouse LD50: 6207 mg/kg; Irritation eyes rabbit: 10 mg/24H severe; investigated as a mutagen and reproductive effector.

18-Hydrate: Oral mouse LD50: > 9 gm/kg; investigated as a mutagen.

-----\Cancer Lists\-----			
Ingredient	---NTP Carcinogen---		IARC Category
	Known	Anticipated	
Aluminum Sulfate (10043-01-3)	No	No	None

12. Ecological Information

Environmental Fate:

No information found.

Environmental Toxicity:

No information found.

13. Disposal Considerations

Whatever cannot be saved for recovery or recycling should be managed in an appropriate

and approved waste disposal facility. Processing, use or contamination of this product may change the waste management options. State and local disposal regulations may differ from federal disposal regulations. Dispose of container and unused contents in accordance with federal, state and local requirements.

14. Transport Information

Not regulated.

15. Regulatory Information

-----\Chemical Inventory Status - Part 1\-----				
Ingredient	TSCA	EC	Japan	Australia
Aluminum Sulfate (10043-01-3)	Yes	Yes	Yes	Yes

-----\Chemical Inventory Status - Part 2\-----				
Ingredient	Korea	DSL	NDL	Phil.
Aluminum Sulfate (10043-01-3)	Yes	Yes	No	No

-----\Federal, State & International Regulations - Part 1\-----				
Ingredient	-SARA 302- RQ	TPQ	-SARA 313- List	Chemical Catg.
Aluminum Sulfate (10043-01-3)	No	No	No	No

-----\Federal, State & International Regulations - Part 2\-----			
Ingredient	CERCLA	-RCRA- 261.33	-TSCA- 8(d)
Aluminum Sulfate (10043-01-3)	5000	No	No

Chemical Weapons Convention: No TSCA 12(b): No CDTA: No
 SARA 311/312: Acute: Yes Chronic: No Fire: No Pressure: No
 Reactivity: No (Mixture / Solid)

Australian Hazchem Code: None allocated.

Poison Schedule: None allocated.

WHMIS:

This MSDS has been prepared according to the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all of the information required by the CPR.

16. Other Information

NFPA Ratings: Health: **2** Flammability: **0** Reactivity: **0**

Label Hazard Warning:

WARNING! HARMFUL IF SWALLOWED OR INHALED. CAUSES IRRITATION TO SKIN, EYES AND RESPIRATORY TRACT.

Label Precautions:

Avoid breathing dust.

Keep container closed.

Use only with adequate ventilation.

Wash thoroughly after handling.

Avoid contact with eyes, skin and clothing.

Label First Aid:

If swallowed, DO NOT INDUCE VOMITING. Give large quantities of water. Never give anything by mouth to an unconscious person. If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. In case of contact, wipe off excess material from skin then immediately flush eyes or skin with plenty of water for at least 15 minutes. Remove contaminated clothing and shoes. Wash clothing before reuse. In all cases, get medical attention.

Product Use:

Laboratory Reagent.

Revision Information:

No Information Found.

Disclaimer:

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